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(54) Title: MEDICAL WARMING DEVICES

(57) Abstract

An intravenous fluid warming device including a warming chamber with phase–change heat storage media, and a conduit through the chamber for passing a fluid through the warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to the fluid.

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Medical Warming Devices

The present invention relates to devices and methods for warming patients. More specifically, the present invention relates to devices and methods for warming patients experiencing hypothermia and warming intravenous fluids.

Background of the Invention

A. Hypothermia

Hypothermia results from exposure to conditions where the body cannot generate sufficient heat to compensate for the body heat lost to the environment. Hypothermia impedes normal bodily functions and, if not reversed, can lead to death. Shivering and peripheral vasoconstriction are the body's primary physiologic mechanisms for generating and conserving heat, respectively.

Hypothermia occurs in conditions where the body is exposed to ambient temperatures well below normal physiologic temperature such as immersion in cold water. Hypothermia also results from the administration of general anesthesia. Under general anesthesia, mammals lose the ability to conserve heat by constriction of peripheral blood vessels ("vasoconstriction") or generate heat by shivering ("thermogenesis") in response to cold challenges. As a result, many individuals emerging from general anesthesia experience hypothermia, particularly if the time under general anesthesia is prolonged.

In general, active core rewarming of the body is desired following (or better yet, during) general anesthesia or other prolonged physiologic exposure to cold. Peritoneal dialysis using warming fluids can be used in cases of severe hypothermia, but this method is invasive and exposes the less severely hypothermic patient to unwarranted risks of morbidity and mortality. Less severe hypothermia can be treated pharmacologically with muscle relaxants, but this intervention decreases shivering which, in turn, impedes physiologic warming and increases the time required to restore normal body temperature. Radiant heat, warm water, or warm air applied to the skin surface alone has only a minimal effect on raising core body temperature because peripheral vasoconstriction impedes heat transfer from the skin to the body core. Breathing warm, humidified air provides some

deep body core heating, and there are devices commercially available for that purpose. Inhalation warming methods, however, are relatively slow-acting and may require invasive techniques such as tracheal intubation for effective use.

The challenge has been to develop a means to rapidly, safely, and effectively bring the core body temperature to within normal physiologic range following general anesthesia or other prolonged exposures to cold. A variety of devices and techniques are known for the therapeutic heating of a part of the body, but these generally are neither designed nor adequate for the transmission of heat to the core of the body. U.S. Pat. No. 4,736,088.

U.S. Pat. No. 4,747,409 describes a sleeve that contains electric resistance heating elements designed to fit over a body extremity for the purpose of dilating blood vessels; and U.S. Pat. No. 5,074,285 describes a device that encloses a human extremity and applies static heat to that extremity simultaneously with a gradient pressure applied repeatedly in timed sequence from a distal to proximal portion of an extremity. Both of these devices will be ineffective for the treatment of hypothermia because heat applied to the surface of the skin in this manner will not allow the heat to penetrate into the body core.

Another device for core body warming uses radio frequency waves. U.S. Pat. No. 4,685,462 describes an apparatus that employs mutually inductive first and second helical coils positioned around the torso of a body to produce radio frequency waves that directly rewarm the body core. This device does not have the flexibility to fit around an appendage and may interfere with surgical intervention of the chest and abdomen. In addition, this device may cause disruptive electromagnetic interference in the operating theater or recovery room following general anesthesia.

U.S. Patent No. 5,683,438 (herein incorporated by reference in its entirety) discloses an apparatus and a method for core body warming of hypothermic mammals. The apparatus has an enclosing element to be placed around a predetermined body portion of a mammal in a vacuum-tight manner and a vacuum system connected to the enclosing element for generating and maintaining a predetermined negative pressure, preferably between - 20 mm Hg and - 80 mm Hg, inside the enclosing element. A heating unit delivers thermal energy while the vacuum system is maintaining the predetermined negative pressure. The simultaneous application of thermal energy and negative pressure

produces vasodilation which promotes absorption of the thermal energy through the surface of the body portion. The circulatory system of the mammal naturally carries the thermal energy to the core body of the mammal. However, the heating means disclosed in this patent are not particularly well suited for the operating room environment.

B. Ambient Temperature IV Fluids

In many medical procedures and situations, it is necessary to administer fluids or liquids of one type or another to a patient. Typically a patient will be given one or more types of liquid medication or hydrating liquids through intravenous administration. Similarly, patients are often provided with transfused blood intravenously. Typical of the types of medical procedures or situations in which fluids are administered include during surgery, in treatment of cardiac arrest, in nurseries, during administration of blood from blood banks, to burn patients and during post-operative recovery.

It is well known that such liquids or fluids should not be at low temperatures when administered to the patients, since the temperature differential between the fluid's temperature and the patient's body temperature can have serious adverse effects upon the patient who is already in a weakened condition e.g. when chilled a patient's circulatory system has less capacity to carry oxygen. The problem of chilling from cold fluids is particularly acute for patients during surgery, when a patient's system is already subject to the trauma of surgery and is also suppressed by the anesthetic, or during treatment for cardiac arrest. See, e.g., Bowen, J. Amer. Assoc. Nurse Anesths., 60, 4, 369-373 (1992); Bostek, J. Amer. Assoc. Nurse Anesths., 60, 6, 561-566 (1992); and Anon., Convention Reporter, 22, 2, 9 (Dec. 1992) [Meeting of Amer. Society of Anesthesiologists (Oct. 1992)].

Unfortunately, however, it is often difficult to deliver fluid to the patient at the appropriate temperature. Many fluids are held in refrigerated storage until just prior to administration to the patient. In addition, it is common practice for operating rooms and recovery rooms to be vigorously air conditioned or to use laminar air flow, both of which keep the ambient temperature quite low. While there are sound medical reasons for this practice, including the comfort of the surgical team during lengthy surgical procedures and

inhibition of infection in the patient, it means that the fluids on hand in the operating room or recovery room will remain at lowered temperatures.

Since it has been recognized that hypothermia of surgical patients is a serious problem, and that use of chilled intravenous or transfused fluids will aggravate that condition and cause further cooling of internal organs, there have been numerous attempts in the past to provide techniques and equipment for heating such fluids prior to administration to the patient. The Bostek and Bowen articles mentioned above describe typical examples. Overall, these various devices have not proved uniformly successful. Stand-alone continuous electric heaters through which the fluids are passed tend to be cumbersome and must be positioned close to the patient, and are thus frequently in the way of the surgical team in what is already normally a very crowded area surrounding the operating table. They also require electrical power cords, and such cords interfere with the surgical team's movements and can be dangerous. In addition, they are costly to purchase and operate. Their use is, therefore, frequently avoided.

Alternatively, there have been efforts to use small tube-like devices which can be preheated and through which the fluid is flowed prior to administration to the patient. Such devices have had shortcomings. Being small, they rapidly cool and after a short time no longer heat the fluid effectively. Further, such devices have been difficult and time consuming to disengage from the fluid flow lines. The result has been that after an initial period of adequate heating, the fluid subsequently administered to the patient is once again in a chilled condition, since the surgical team members do not have the time to engage in lengthy disassembly, reheating and replacement of these devices.

Since the problem of hypothermia in patients and the aggravating effects of administration of chilled fluids is an on-going problem, it would therefore be advantageous to have a simple method for providing heat to these fluids, using a device of a sufficiently simple design that each unit could be quickly and easily replaced with another heated unit when the heating effect of the first significantly diminished. The fluids administered to the patients would therefore be kept substantially uniformly at the desirable administration temperature during the entire surgical procedure.

The ambient temperature in hospitals is usually kept fairly low, and IV solutions equilibrate with the ambient temperature. At typical fluid administration rates, the

differential between the IV fluid temperature and body temperature is insignificant to lower core body temperature. At high fluid administration rates, cooling of core temperature can be a major concern.

While IV fluid administration is not generally a cause of body cooling, ambient temperature fluids can have significant local effects in the region of the IV catheter site. In general, fluids at temperatures below body temperature tend to cause venospasm. This may lead to increased risk of sterile thrombophlebitis and shorten IV catheter dwell time. The cold solutions may also cause increased pain at the catheter site.

Fluids warmed to or slightly above body temperature may be advantageous by increasing the dwell time of an IV catheter, reducing the risk of thrombophlebitis and improving patient comfort. These effects may be primarily by reducing venospasm, thus allowing blood to flow around the catheter as it returns to the central circulation. By increasing the caliber of the vessel, the tip of the catheter is less likely to irritate the fragile endothelial lining of the vein.

Recently, Elltec, Co., Ltd. introduced the Animec AM-25 electric infusion fluid warmer. This in-line device warms fluid in the IV tubing leading to the IV catheter. The main drawback of this device is that it is electric, a potential source of multiple hazards in a hospital. Also, since the device has no battery back-up, it only works when the patient is in proximity of an electric outlet.

U.S. Patent No. 5,683,381 discloses a microwave apparatus for warming of a liquid such as blood or IV fluids in which the warming occurs in-line by means of a microwave heating cavity having a source of microwave energy coupled thereto. A support element in the form of a bobbin forms an assembly with an IV tube wound about the bobbin. This tubing-bobbin assembly is inserted into the microwave heating cavity. A non-invasive, non-perturbing microwave temperature monitor is provided coupled to the microwave heating cavity for monitoring the temperature of liquid flowing in the IV tube. Controls are provided including a desired operating selector for combining signals representative of, not only cavity temperature, but also inlet and outlet temperatures to control the power level of microwave energy delivered to the heating cavity.

U.S. Patent No. 5,690,614 describes a microwave heating apparatus for warming low flow rate infusates includes an electrically conductive housing defining an elongated

heating cavity and a printed circuit board which separates the cavity lengthwise into first and second cavity sections. The circuit board includes a substrate which provides a fluid-tight divider between the two cavity sections and a meandering conductor run which extends along the substrate.

Another method is disclosed in U.S. Patent No. 5,370,674 to avoid hypothermia and other adverse effects of administration of chilled fluids such as intravenous medicating fluid, an intravenous hydrating fluid or blood to a patient during medical procedures such as surgery and post-operative recovery. The method provides heat to such fluids, using an elasticized heating device such that each unit can be quickly and easily replaced with another unit when the heating effect of the first is significantly diminished, so that the fluid administered is kept at the desirable administration temperature during the entire surgical procedure. The method involves providing a conduit through which the fluid is administered to the patient (usually intravenously or subcutaneously). The elasticized device includes a semi-solid composition with a relatively high heat capacity. The device is preheated and wrapped around a length of the conduit so that the fluid passing through the conduit is heated to the desired temperature immediately prior to administration of the fluid to the patient. Use of two or more devices simultaneously is also disclosed. Further, as the heat content of one device is depleted, the method also includes quick replacement of that device with another, previously preheated, so that the heating of the fluid continues substantially continuously at the desire temperature.

It would be advantageous to provide devices for warming such fluids that do not suffer from these disadvantages. The present invention provides such devices and methods.

Summary of the Invention

The present invention further relates to an intravenous fluid warming device including (a) a warming chamber including a phase-change heat storage media, and (b) a conduit through the chamber for passing a fluid through the warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid.

This embodiment may be used to prevent local hypothermia, which may lead to complications in the vicinity of the catheter introduction site.

The present invention relates to a system and method for treating a mammal experiencing hypothermia, said system including (a) an enclosing means for enclosing a body portion of the mammal with a receiving means for receiving a phase-change heat storage media; (b) a sealing means mounted on the enclosing means for establishing a vacuum-tight fit between said body portion and the enclosing means; (c) a vacuum system connected to the enclosing means for generating and maintaining a predetermined negative pressure inside the enclosing means, thereby causing vasodilation in the body portion; and (d) a phase-change heat storage media for delivering thermal energy to the surface of said body portion while said vacuum system is maintaining said predetermined negative pressure, so that the local vasodilation in said body portion promotes absorption and transfer of said thermal energy from the surface of the body portion to the core body of the mammal.

Brief Description of the Drawings

Figure 1 depicts a device for treating a patient suffering from hypothermia in accordance with the present invention.

Figure 2 depicts a device for warming.

Figure 3 is a heat pipe.

Detailed Description of the Invention

Methods and devices for treating hypothermia and/or warming intravenous fluids are disclosed. The methods and devices include the use of phase-change heat transfer media.

Phase-Change Heat Storage Media

Phase-change heat storage media in accordance with the present invention include any heat storage media that will release heat slowly once heated up to its phase-change temperature. For example, phase-change media in accordance with the present invention include eutectic salts, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, and polyethylene glycol 8000. Other phase-change heat storage media include organic compounds with heats of fusion of 35 to 45 cal/g. Still other phase-change heat storage media include organic compounds with heats of fusion such that the combination of the heat of fusion with other temperature influencing parameters of the system or device are selected to achieve a suitable temperature. For example, a phase-change heat storage media could include compounds with higher heat of fusion if there are sufficient cooling influences such as conduit length between the media and the patient.

Examples of eutectic salts include sodium sulfate decahydrate (melting point 32.degree. C., heat of fusion 51 cal/g), calcium chloride hexahydrate (melting point 30.degree. C., heat of fusion 40.7 cal/g), sodium carbonate decahydrate (melting point 32.5 to 34.5.degree. C.), calcium nitrate tetrahydrate (melting point 39.7.degree. to 2.7.degree. C.) and sodium thiosulfate pentahydrate (melting point 40.degree. to 45.degree. C.). Those of ordinary skill in the art will appreciate that mixtures of eutectic salts can be made to arrive at a mixture having a desired melting point.

Other phase-change heat storage media include other salt hydrates, high density polyethylene, and CARBOWAX.™ (Union Carbide Corporation, Danbury, Conn., U.S.A.)

Other phase-change heat storage media in accordance with the present invention include those disclosed in U.S. Patent Nos. 5,424,519 and US 5,630,961 for a thermal storage mixtures that can be microwaved and maintain a constant temperature for extended periods of time.

It is also possible to use other heat storage media that do not include a phase change mechanism so long as the heat storage media is capable of maintaining an elevated temperature between 80°F and 110°F for at least 3 hours in ambient 70°F air environment.

Phase transfer heat storage media in accordance with the present invention may be stabilized in small particle sizes, e.g., 5 to 10 mm in diameter or smaller. They may also be mixed with filler materials, etc.

Microwave-Activated Intravenous Fluid Warmer

An inexpensive, easy to use, IV fluid warming system based on thermal storage technology is disclosed. The system includes a warming chamber with phase-change heat storage media and a conduit through the chamber for passing a length of intravenous tubing containing a fluid through the warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid. Since IV fluids are often run at different rates depending on the needs, size, weight and condition of the patient, several approached to maintaining an appropriate fluid temperature are contemplated. Thermal storage materials can be combined to produce the desired heat, the volume of the thermal storage material can be varied depending on the fluid flow rate, the number of packets of thermal material within the chamber can be varied, or the number of loops of IV tubing passing through the chamber can be varied. In this way, a precise temperature can be maintained at a variety of flow rates.

The fluid warming chamber includes a phase-change heat storage media or other heat storage media. The phase-change heat storage media or other heat storage media is described above and may be further insulated, encapsulated or mixed with filler. Preferably, the phase-change heat storage media is contained in a flexible bag which is microwaved and placed in the warming chamber. Standard IV tubing can then be looped in the chamber before it is closed, thus eliminating the need for a special tubing set. The number of loops contained in the chamber will be proportional to the flow rate set, to maintain a constant temperature.

The conduit is any means for passing a fluid through the warming chamber. For example, several loops of IV tubing can be passed through the warming chamber.

In use, the device could be in close proximity to the connection of the IV tubing to the IV catheter and the IV tubing would be a disposable product. The chamber could have a Velcro strap or other means to connect it to a patient's extremity, or could be worn as a glove or sleeve.

Alternatively, larger quantities of phase-change heat storage media may be used than may be comfortably worn by the patient. To accommodate the use of large amounts of phase-change heat storage media, the warming chamber may include an insulated container placed at some distance from the patient. The exact size and distance will depend on the temperature the phase-change heat storage media. For example coils of tubing in a cassette that snap into an insulated container with phase-change heat storage media inside may be used. At periodic intervals, a nurse or aide would heat several such containers in a microwave oven and then exchange the newly "charged" containers with the ones in use on patients. The cooled containers could then be re-microwaved before the next charge. This would also serve the purpose of killing all bacterial contamination, thus eliminating the need for using specific containers with specific patients.

Preferably, a thermal strip on the chamber indicates the temperature of the warming chamber. The warming chamber is also preferably designed so that the thermal storage package maintains a temperature of ~ 41C for a period of 8-12 hours and warm the fluid to ~ 37C at a fluid flow rate of 125ml/H. At the end of that time, the package would be removed and re-microwaved.

Microwaving would not only restore the thermal storage material to the desired temperature, but would also sterilize the package. Since fluids running at slower or faster rates would be warmer or cooler, respectively, the number of loops of IV tubing in the chamber could be varied, or the size of the thermal package or number of packages could be varied depending on the flow rate.

A medical port (i.e. stopcock) can also be located distal to the chamber (between it and the IV catheter) to administer medications that are heat labile.

The present invention has the advantages of low cost, simple design and operation, and easy sterilization, increased IV catheter life, reducing complications, and reducing pain.

Figure 2 depicts an intravenous fluid warmer in accordance with the present invention. Warming chamber 1 includes phase-change heat storage media 3 with an insulation coating on the outside a hinge 18, and locking mechanism 20, velcro straps 16 and conduit 4. In use, the phase-change heat storage media 3 is preheated by inserting the insulated container with inner chamber 1 into a microwave oven. Conduit 4 is placed

inside chamber 1 and closed with locking mechanism 20. Conduit 4 is then placed in-line with fusion pump 6, roller clamp 8, intravenous tubing 10, intravenous tube set 10 and intravenous bag 14.

When it is desired to place the container at some distance from the patient, thus increasing the potential for the material to cool, especially at low flow rates, various heating means may be used to provide a heated conduit between the container and the patient. For example, insulated tubing may be used. Similarly, a "heat pipe" such as that depicted in figure 3 for efficiently heating or dissipating fluid may also be used. The "heat pipe" may be connected to the insulated container and maintain the fluid in the IV tubing at a constant temperature at even a considerable distance from the patient. It may also be configured so that the conduit may be removed and the heat pipe reused.

A heat pipe, such as a copper/water type, may be used to convey heat to the conduit from the phase-change heat storage media to the i.v. fluid. The pipe may be bent to run parallel to the fluid line, and enclosed in an insulating cylinder to retain heat during transfer. This cylinder may be hinged for easy access and may also be transparent. An example is depicted in Figure 3 and includes a conduit for i.v. fluid 70, a conduit for phase-change heat storage media 72, an insulating cylinder 74 (e.g. polymethylmethacrylate) and a handle 76 for opening valves. Other heat pipes would include axially grooved heat pipes, composite heat pipes, and loop heat pipes. The use of heat pipes may require the use of a holder that anchors the heat pipe so that the additional weight of the pipe will not pull the i.v. line out of the patient.

Apparatus and Method Using a Thermal Storage Mixture for the Treatment of Hypothermia

Recently, Dennis A. Grahn of Stanford University was granted a patent, U.S. Patent No. 5,683,438 for a "Apparatus and Method for Core Body Warming of Mammals Experiencing Hypothermia", the disclosure of which is hereby incorporated by reference ("the Grahn patent"). The system described by Grahn requires a "heating means" for delivering thermal energy to a patient's extremity in an enclosed, rigid, vacuum-tight container. The heating means described both in the specification and in the claims is a circulating warm water bath, heating blanket, or heat lamp.

The enclosing means of the present invention is any means for enclosing a portion of a patients body such as an enclosing element in the form of a hollow, tubular elongated sleeve. The enclosing means is preferably particularly adapted to the shape of the body part being enclosed. The enclosing means can be formed of any material capable of sustaining the negative pressure of the vacuum, e.g. a neoprene-impregnated polyester sheath supported on a spring steel wire helix. For easier storage, an inflatable device that is rigid when inflated may be used. The enclosing means further includes means for receiving phase-change heat storage media. Such receiving means can be for example a space or void, groove, slot, etc. Any receiving means that will permit the phase-change heat storage media to come into direct or indirect contact with the patient will suffice.

Sealing means can be any means for creating an airtight seal about the enclosing means including, for example, a flexible flange. Any adhesive or "sticky" means, plus a flexible means. Shouldn't use pressure as it will reduce flow.

The vacuum system is any vacuum system capable of creating a reduced pressure within the enclosing means. Many suitable systems are known to those of ordinary skill in the art. In one embodiment, the vacuum pressure modulates to imitate circulation.

The present invention includes phase-change heat storage media for delivering thermal energy to the surface of the body. Any phase-change heat storage media as described above can be used. The use of phase-change heat storage media has several advantages over the use of a heating lamp, circulating warm water bath and warming blanket. For example, all of these other heating devices require the presence of electrical cords, tubing, or other conduits to the body surface being warmed. The present invention does not require any such conduits. The phase-change heat storage media is simply warmed at a site external from the body part being heated. The phase-change heat storage media may then be placed in direct or indirect contact (e.g. stocking as with a cast) with the body part being heated within the enclosing means. For example, the phase-change heat storage media disclosed in U.S. Patent Nos. 5,424,519 and 5,630,961 may be heated in a microwave and then inserted into the enclosing means. Phase-change heat storage materials are particularly advantageous for this application because they store large quantities of energy at a precise temperature for long periods of time. This reduces the need to change the material frequently and prevents the occurrence of skin damage.

Preferably, the phase-change heat storage media is enclosed in a thin flexible container and inserted into the enclosing means in contact with the body part being warmed. Phase-change heat transfer media are uniquely able to maintain a constant temperature over time without outside adjustment and monitoring. Once they achieve the phase transition temperature, they remain at that temperature until the phase change is complete. Therefore, there can be no overheating or under heating, which are problems with conventional electric heaters, water baths, and heating lamps.

Another benefit of the present invention over the Grahn patent is the use of a thermal storage mixture that can be microwaved. This will reduce the cost and complexity of the system by removal of the water bath components. Additionally, the thermal storage mixture is reusable and would be sterilized each time it was microwaved. Thus, a body warming system utilizing the thermal storage mixture would reduce the cost and improve the efficacy and safety of the device.

As shown in FIG. 1, a preferred embodiment of the present invention is a core body warming apparatus 10 with an enclosing element 12 in the form of a hollow, tubular, elongated sleeve. Sleeve 12 is dimensioned to fit around a body portion 62, preferably an appendage, as described below. In the embodiment illustrated in FIG. 1 appendage 62 is an arm.

Sleeve 12 can be made of virtually any non-hazardous material which retains the requisite shape while the interior of sleeve 12 is maintained at negative pressures. In particular, sleeve 12 has to support negative pressures down to at least - 85 mm Hg. In a preferred embodiment sleeve 12 is made of pliant and elastic materials which can include supporting or reinforcing members. This type of construction easily accommodates movements of arm 62 and thus provides a hypothermic patient more comfort and freedom. In the present embodiment sleeve 12 is a neoprene-impregnated polyester sheath supported on a spring steel wire helix.

Sleeve 12, as shown in FIG. 1, has a distal end or rim 14 and a proximal end or rim 16. Distal rim 14 is capped by a sealing element 60 capable of creating an airtight seal. In this embodiment element 60 is a plastic plate. However, a cap or other sealing element can be used with equal success. In fact, sleeve 12 may be closed off at distal end 14.

A flexible flange 20 is attached to proximal rim 16. Flange 20 is preferably made of a synthetic material impermeable to air. The tubular form of flange 20 ensures that it fits snugly around arm 62 and conforms to the arm's shape. In the present embodiment 20 is made of Neoprene (R).

Elongated sleeve 12 is provided with a pressure inlet 22. A pressure conduit 24, e.g., a flexible tube, is connected to inlet 22. The other end of conduit 24 is connected to a vacuum pump 26. Vacuum pump 26 is a standard pump capable of generating negative pressures down to - 85 mm Hg and beyond inside sleeve 12. The delivery of this negative pressure through conduit 24 can be regulated by any conventional mechanisms. In the embodiment shown, an adjustable valve 28 guarantees maintenance of the desired pressure inside sleeve 12. Conveniently, a readout gauge 32 is also provided for visual pressure indication.

A phase-transfer heat storage media 34 is lodged inside elongated sleeve 12. Core body warming apparatus 10 is simple to use. First, a hypothermic person's arm 62 is placed inside sleeve 12 such that the preheated phase-transfer heat storage media 34 envelops arm 62 and remains in contact with it. In this position, flange 20 wraps around the upper portion of arm 62. To ensure that flange 20 conforms closely to the contour of the upper portion of arm 62 the latter is preferably bare.

With arm 62 properly inserted into sleeve 12, pump 26 is activated to produce a negative pressure between - 20 mm Hg and - 85 mm Hg inside sleeve 12. Under the influence of negative pressure or suction, flange 20 seals tightly around the upper part of arm 62 to preserve the vacuum inside sleeve 12.

Claims

1. An intravenous fluid warming device comprising:

a) a warming chamber comprising phase-change heat storage media, and;

b) a conduit through said chamber for passing a fluid through said warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid.

2. The warming device of claim 1, wherein said phase-change heat storage media comprise eutectic salt, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, or polyethylene glycol 8000 or mixtures thereof.

3. The intravenous fluid warming device of claim 1, wherein said conduit is shaped in the form of coils.

4. The intravenous fluid warming device of claim 1, wherein said chamber is an insulated chamber.

5. The intravenous fluid warming device of claim 4, wherein said insulted chamber is shaped in the form of a cassette.

6. The intravenous fluid warming device of claim 1, wherein said phase-change heat storage media is in the form of beads.

7. The intravenous fluid warming device of claim 1, further comprising a flexible bag containing said phase-change heat storage media.

8. The intravenous fluid warming device of claim 1, said conduit extending from said chamber to a patient in need of intravenous fluid administration.

9. The intravenous fluid warming device of claim 1, further comprising an intravenous port in fluid communication with said conduit.

10. The intravenous fluid warming device of claim 8, further comprising a heat pipe for warming said conduit.

11. The intravenous fluid warming device of claim 10, wherein said heat pipe is insulated.

12. The intravenous fluid warming device of claim 10, wherein said heat pipe comprises a second conduit for said phase-change heat storage media.

13. The intravenous fluid warming device of claim 1, wherein said phase-change heat storage media is microwave heatable.

14. The intravenous fluid warming device of claim 1, wherein said warming chamber is formed from said phase-change heat storage media.

15. A system for treating a mammal experiencing hypothermia, said system comprising:

a) an enclosing means for enclosing a body portion of said mammal with a means for receiving a phase-change heat storage media;

b) a sealing means mounted on said enclosing means for establishing a vacuum-tight fit between said body portion and said enclosing means;

c) a vacuum system connected to said enclosing means for generating and maintaining a predetermined negative pressure inside said enclosing means, thereby causing vasodilation in said body portion; and

d) a phase-change heat storage media for delivering thermal energy to the surface of said body portion while said vacuum system is maintaining said predetermined negative pressure, so that the local vasodilation in said body portion promotes absorption and transfer of said thermal energy from the surface of said body portion to the core body of said mammal.

16. The warming device of claim 15, wherein said phase-change heat storage media comprise eutectic salt, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, or polyethylene glycol 8000 or mixtures thereof.

17. A method for core body warming of a mammal experiencing hypothermia, said method comprising the steps of:

a) enclosing a body portion of said mammal in a vacuum-tight manner, thereby defining an enclosure;

b) generating and maintaining a negative pressure within said enclosure, thereby causing a local vasodilation in said body portion; and

c) delivering a thermal energy to a surface of said body portion with a heat storage media while maintaining said negative pressure, so that said local vasodilation promotes absorption and transfer of said thermal energy from said surface to a core body of said mammal.

18. A method for intravenous administration of fluid comprising warming said fluid with a phase-change heat storage media and administering said fluid intravenously.

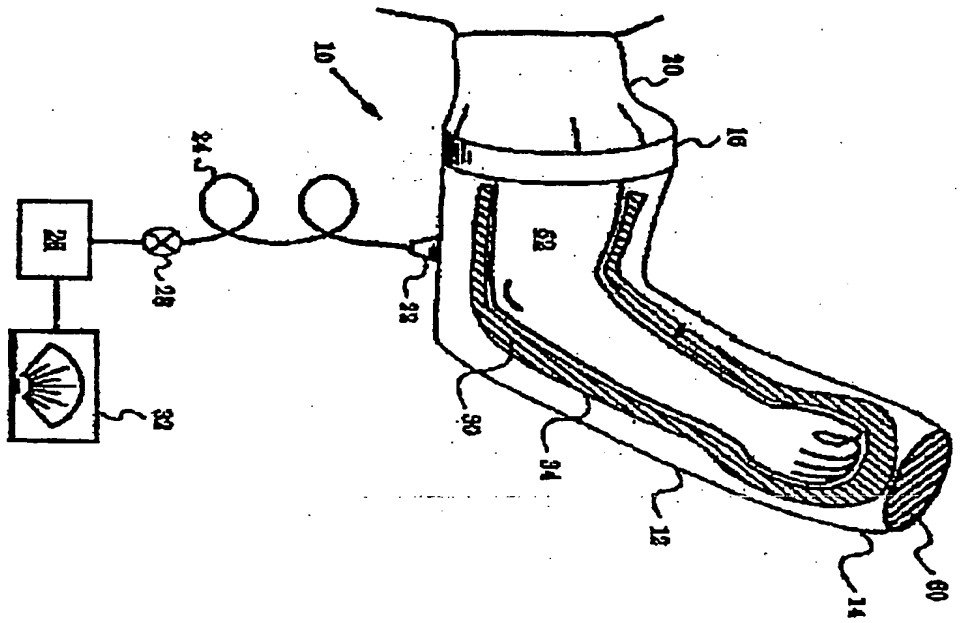

Figure 1

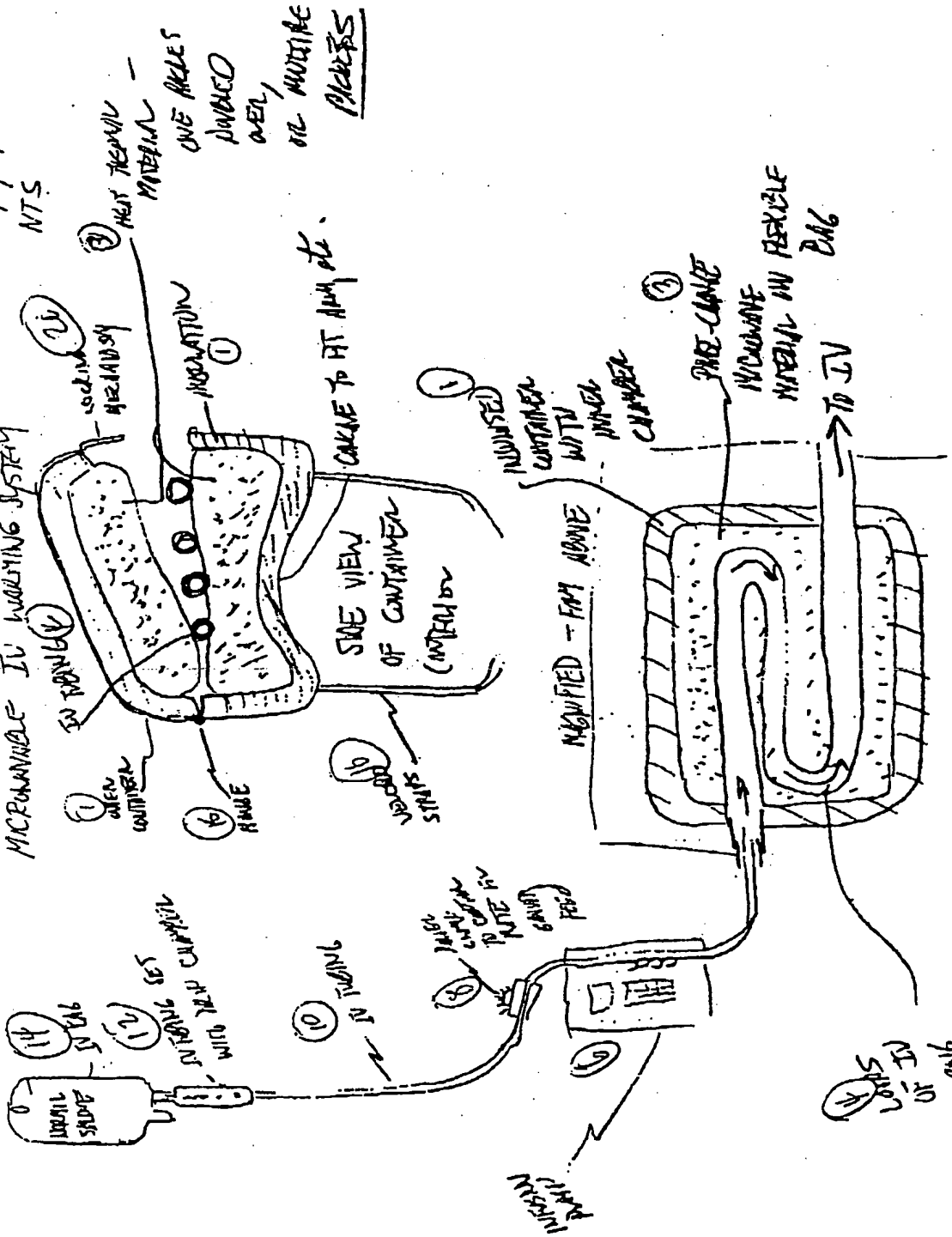

Figure 2

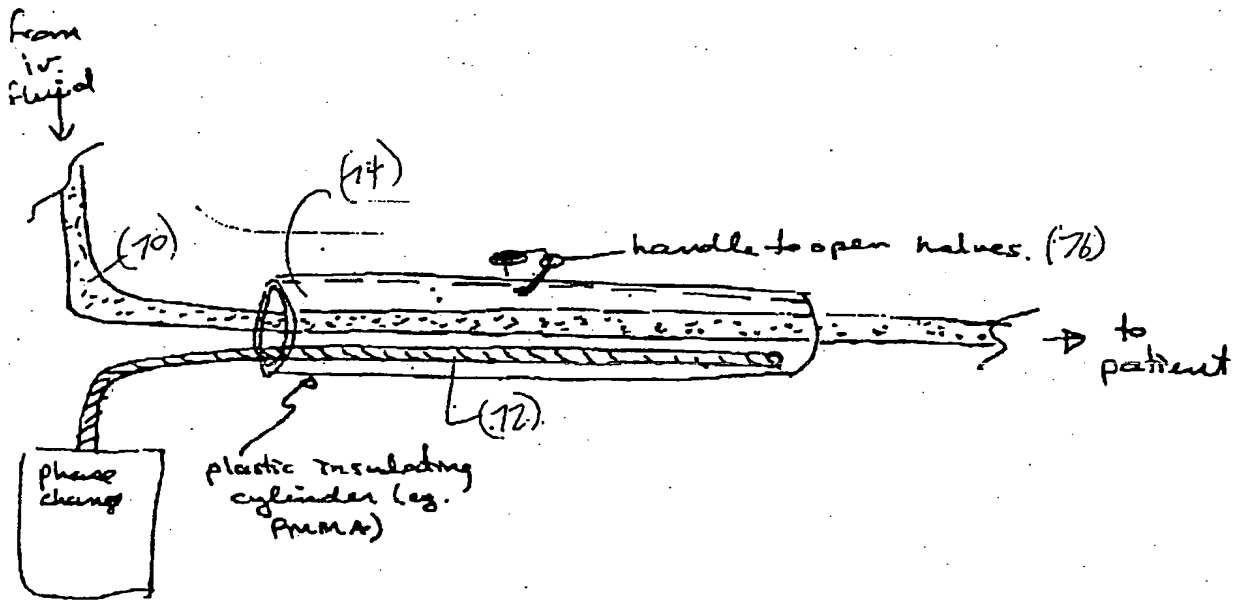
from
iv.
fluid
(14)
(10)
handle to open valves. (16)
to
patient
(12)
plastic insulating
cylinder (eg.
PMMA)
phase
change

Figure 3

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(71) Applicant: UNIVERSITY OF FLORIDA RESEARCH FOUNDATION [US/US]; 186 Grinter Hall, Gainesville, FL 32611-5500 (US).

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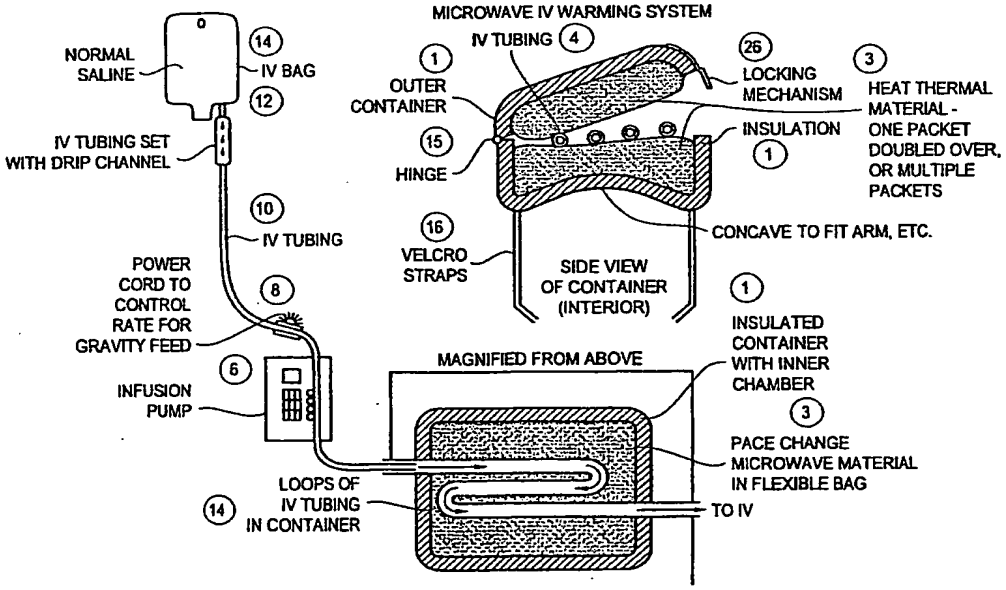
(54) Title: MEDICAL WARMING DEVICES



(57) Abstract: This invention is an n intravenous fluid warming device including a warming chamber (1) with a phase change heat storage media (3), and a conduit (4) through the chamber (1) for passing a fluid through the warming chamber (1) with a length and diameter sufficient to provide a desired level of thermal energy to the fluid.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/03976

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US CL :607/104

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Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/104-106, 113, 114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,370,674 A (FARRELL) 6 December 1994.	1, 3, 4, 7-14 --- 2, 5, 6, 18
X --- Y	US 5,683,438 A (GRAHN) 04 November 1997.	15 --- 16, 17
Y,P	US 5,984,953 A (SABIN et al.) 16 November 1999, col 8 lines 64-67.	2, 6, 16
Y	US 4,919,134 A (STREETER) 24 April 1990.	5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOCELYN RAM Telephone No. (703) 308-6392

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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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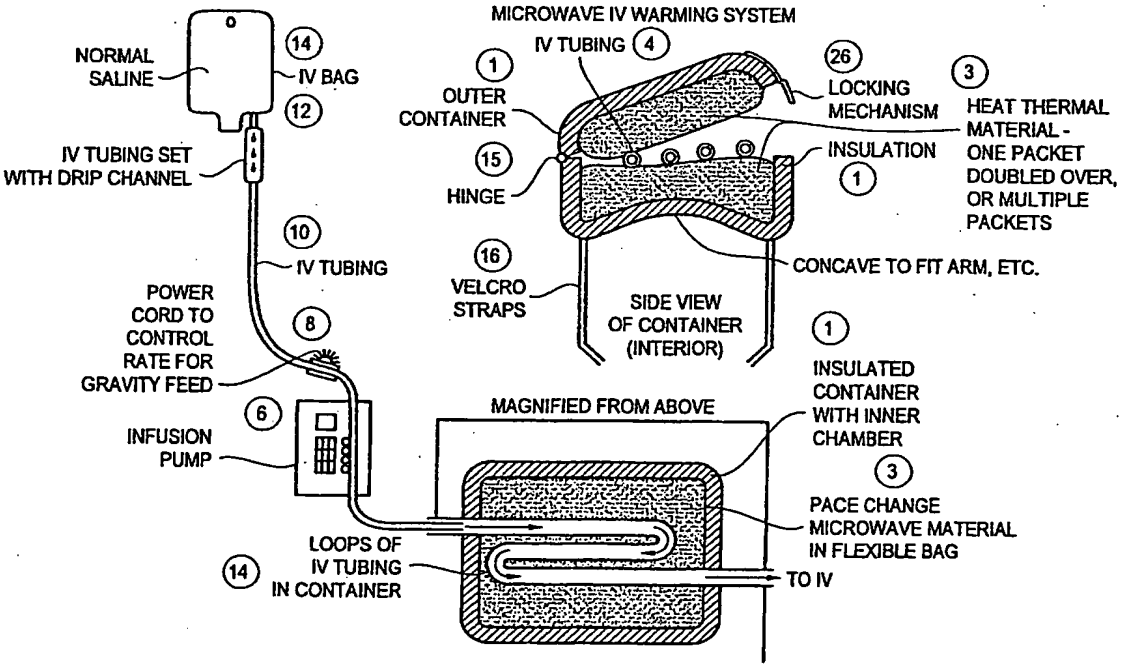
(54) Title: MEDICAL WARMING DEVICES



(57) Abstract: This invention is an n intravenous fluid warming device including a warming chamber (1) with a phase change heat storage media (3), and a conduit (4) through the chamber (1) for passing a fluid through the warming chamber (1) with a length and diameter sufficient to provide a desired level of thermal energy to the fluid.

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Medical Warming Devices

The present invention relates to devices and methods for warming patients. More specifically, the present invention relates to devices and methods for warming patients experiencing hypothermia and warming intravenous fluids.

Background of the Invention

A. Hypothermia

Hypothermia results from exposure to conditions where the body cannot generate sufficient heat to compensate for the body heat lost to the environment. Hypothermia impedes normal bodily functions and, if not reversed, can lead to death. Shivering and peripheral vasoconstriction are the body's primary physiologic mechanisms for generating and conserving heat, respectively.

Hypothermia occurs in conditions where the body is exposed to ambient temperatures well below normal physiologic temperature such as immersion in cold water. Hypothermia also results from the administration of general anesthesia. Under general anesthesia, mammals lose the ability to conserve heat by constriction of peripheral blood vessels ("vasoconstriction") or generate heat by shivering ("thermogenesis") in response to cold challenges. As a result, many individuals emerging from general anesthesia experience hypothermia, particularly if the time under general anesthesia is prolonged.

In general, active core rewarming of the body is desired following (or better yet, during) general anesthesia or other prolonged physiologic exposure to cold. Peritoneal dialysis using warming fluids can be used in cases of severe hypothermia, but this method is invasive and exposes the less severely hypothermic patient to unwarranted risks of morbidity and mortality. Less severe hypothermia can be treated pharmacologically with muscle relaxants, but this intervention decreases shivering which, in turn, impedes physiologic warming and increases the time required to restore normal body temperature. Radiant heat, warm water, or warm air applied to the skin surface alone has only a minimal effect on raising core body temperature because peripheral vasoconstriction impedes heat transfer from the skin to the body core. Breathing warm, humidified air provides some

deep body core heating, and there are devices commercially available for that purpose. Inhalation warming methods, however, are relatively slow-acting and may require invasive techniques such as tracheal intubation for effective use.

The challenge has been to develop a means to rapidly, safely, and effectively bring the core body temperature to within normal physiologic range following general anesthesia or other prolonged exposures to cold. A variety of devices and techniques are known for the therapeutic heating of a part of the body, but these generally are neither designed nor adequate for the transmission of heat to the core of the body. U.S. Pat. No. 4,736,088.

U.S. Pat. No. 4,747,409 describes a sleeve that contains electric resistance heating elements designed to fit over a body extremity for the purpose of dilating blood vessels; and U.S. Pat. No. 5,074,285 describes a device that encloses a human extremity and applies static heat to that extremity simultaneously with a gradient pressure applied repeatedly in timed sequence from a distal to proximal portion of an extremity. Both of these devices will be ineffective for the treatment of hypothermia because heat applied to the surface of the skin in this manner will not allow the heat to penetrate into the body core.

Another device for core body warming uses radio frequency waves. U.S. Pat. No. 4,685,462 describes an apparatus that employs mutually inductive first and second helical coils positioned around the torso of a body to produce radio frequency waves that directly rewarm the body core. This device does not have the flexibility to fit around an appendage and may interfere with surgical intervention of the chest and abdomen. In addition, this device may cause disruptive electromagnetic interference in the operating theater or recovery room following general anesthesia.

U.S. Patent No. 5,683,438 (herein incorporated by reference in its entirety) discloses an apparatus and a method for core body warming of hypothermic mammals. The apparatus has an enclosing element to be placed around a predetermined body portion of a mammal in a vacuum-tight manner and a vacuum system connected to the enclosing element for generating and maintaining a predetermined negative pressure, preferably between - 20 mm Hg and - 80 mm Hg, inside the enclosing element. A heating unit delivers thermal energy while the vacuum system is maintaining the predetermined negative pressure. The simultaneous application of thermal energy and negative pressure

produces vasodilation which promotes absorption of the thermal energy through the surface of the body portion. The circulatory system of the mammal naturally carries the thermal energy to the core body of the mammal. However, the heating means disclosed in this patent are not particularly well suited for the operating room environment.

B. Ambient Temperature IV Fluids

In many medical procedures and situations, it is necessary to administer fluids or liquids of one type or another to a patient. Typically a patient will be given one or more types of liquid medication or hydrating liquids through intravenous administration. Similarly, patients are often provided with transfused blood intravenously. Typical of the types of medical procedures or situations in which fluids are administered include during surgery, in treatment of cardiac arrest, in nurseries, during administration of blood from blood banks, to burn patients and during post-operative recovery.

It is well known that such liquids or fluids should not be at low temperatures when administered to the patients, since the temperature differential between the fluid's temperature and the patient's body temperature can have serious adverse effects upon the patient who is already in a weakened condition e.g. when chilled a patient's circulatory system has less capacity to carry oxygen. The problem of chilling from cold fluids is particularly acute for patients during surgery, when a patient's system is already subject to the trauma of surgery and is also suppressed by the anesthetic, or during treatment for cardiac arrest. See, e.g., Bowen, J. Amer. Assoc. Nurse Anesths., 60, 4, 369-373 (1992); Bostek, J. Amer. Assoc. Nurse Anesths., 60, 6, 561-566 (1992); and Anon., Convention Reporter, 22, 2, 9 (Dec. 1992) [Meeting of Amer. Society of Anesthesiologists (Oct. 1992)].

Unfortunately, however, it is often difficult to deliver fluid to the patient at the appropriate temperature. Many fluids are held in refrigerated storage until just prior to administration to the patient. In addition, it is common practice for operating rooms and recovery rooms to be vigorously air conditioned or to use laminar air flow, both of which keep the ambient temperature quite low. While there are sound medical reasons for this practice, including the comfort of the surgical team during lengthy surgical procedures and

inhibition of infection in the patient, it means that the fluids on hand in the operating room or recovery room will remain at lowered temperatures.

Since it has been recognized that hypothermia of surgical patients is a serious problem, and that use of chilled intravenous or transfused fluids will aggravate that condition and cause further cooling of internal organs, there have been numerous attempts in the past to provide techniques and equipment for heating such fluids prior to administration to the patient. The Bostek and Bowen articles mentioned above describe typical examples. Overall, these various devices have not proved uniformly successful. Stand-alone continuous electric heaters through which the fluids are passed tend to be cumbersome and must be positioned close to the patient, and are thus frequently in the way of the surgical team in what is already normally a very crowded area surrounding the operating table. They also require electrical power cords, and such cords interfere with the surgical team's movements and can be dangerous. In addition, they are costly to purchase and operate. Their use is, therefore, frequently avoided.

Alternatively, there have been efforts to use small tube-like devices which can be preheated and through which the fluid is flowed prior to administration to the patient. Such devices have had shortcomings. Being small, they rapidly cool and after a short time no longer heat the fluid effectively. Further, such devices have been difficult and time consuming to disengage from the fluid flow lines. The result has been that after an initial period of adequate heating, the fluid subsequently administered to the patient is once again in a chilled condition, since the surgical team members do not have the time to engage in lengthy disassembly, reheating and replacement of these devices.

Since the problem of hypothermia in patients and the aggravating effects of administration of chilled fluids is an on-going problem, it would therefore be advantageous to have a simple method for providing heat to these fluids, using a device of a sufficiently simple design that each unit could be quickly and easily replaced with another heated unit when the heating effect of the first significantly diminished. The fluids administered to the patients would therefore be kept substantially uniformly at the desirable administration temperature during the entire surgical procedure.

The ambient temperature in hospitals is usually kept fairly low, and IV solutions equilibrate with the ambient temperature. At typical fluid administration rates, the

differential between the IV fluid temperature and body temperature is insignificant to lower core body temperature. At high fluid administration rates, cooling of core temperature can be a major concern.

While IV fluid administration is not generally a cause of body cooling, ambient temperature fluids can have significant local effects in the region of the IV catheter site. In general, fluids at temperatures below body temperature tend to cause venospasm. This may lead to increased risk of sterile thrombophlebitis and shorten IV catheter dwell time. The cold solutions may also cause increased pain at the catheter site.

Fluids warmed to or slightly above body temperature may be advantageous by increasing the dwell time of an IV catheter, reducing the risk of thrombophlebitis and improving patient comfort. These effects may be primarily by reducing venospasm, thus allowing blood to flow around the catheter as it returns to the central circulation. By increasing the caliber of the vessel, the tip of the catheter is less likely to irritate the fragile endothelial lining of the vein.

Recently, Elltec, Co., Ltd. introduced the Animec AM-25 electric infusion fluid warmer. This in-line device warms fluid in the IV tubing leading to the IV catheter. The main drawback of this device is that it is electric, a potential source of multiple hazards in a hospital. Also, since the device has no battery back-up, it only works when the patient is in proximity of an electric outlet.

U.S. Patent No. 5,683,381 discloses a microwave apparatus for warming of a liquid such as blood or IV fluids in which the warming occurs in-line by means of a microwave heating cavity having a source of microwave energy coupled thereto. A support element in the form of a bobbin forms an assembly with an IV tube wound about the bobbin. This tubing-bobbin assembly is inserted into the microwave heating cavity. A non-invasive, non-perturbing microwave temperature monitor is provided coupled to the microwave heating cavity for monitoring the temperature of liquid flowing in the IV tube. Controls are provided including a desired operating selector for combining signals representative of, not only cavity temperature, but also inlet and outlet temperatures to control the power level of microwave energy delivered to the heating cavity.

U.S. Patent No. 5,690,614 describes a microwave heating apparatus for warming low flow rate infusates includes an electrically conductive housing defining an elongated

heating cavity and a printed circuit board which separates the cavity lengthwise into first and second cavity sections. The circuit board includes a substrate which provides a fluid-tight divider between the two cavity sections and a meandering conductor run which extends along the substrate.

Another method is disclosed in U.S. Patent No. 5,370,674 to avoid hypothermia and other adverse effects of administration of chilled fluids such as intravenous medicating fluid, an intravenous hydrating fluid or blood to a patient during medical procedures such as surgery and post-operative recovery. The method provides heat to such fluids, using an elasticized heating device such that each unit can be quickly and easily replaced with another unit when the heating effect of the first is significantly diminished, so that the fluid administered is kept at the desirable administration temperature during the entire surgical procedure. The method involves providing a conduit through which the fluid is administered to the patient (usually intravenously or subcutaneously). The elasticized device includes a semi-solid composition with a relatively high heat capacity. The device is preheated and wrapped around a length of the conduit so that the fluid passing through the conduit is heated to the desired temperature immediately prior to administration of the fluid to the patient. Use of two or more devices simultaneously is also disclosed. Further, as the heat content of one device is depleted, the method also includes quick replacement of that device with another, previously preheated, so that the heating of the fluid continues substantially continuously at the desire temperature.

It would be advantageous to provide devices for warming such fluids that do not suffer from these disadvantages. The present invention provides such devices and methods.

Summary of the Invention

The present invention further relates to an intravenous fluid warming device including (a) a warming chamber including a phase-change heat storage media, and (b) a conduit through the chamber for passing a fluid through the warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid.

This embodiment may be used to prevent local hypothermia, which may lead to complications in the vicinity of the catheter introduction site.

The present invention relates to a system and method for treating a mammal experiencing hypothermia, said system including (a) an enclosing means for enclosing a body portion of the mammal with a receiving means for receiving a phase-change heat storage media; (b) a sealing means mounted on the enclosing means for establishing a vacuum-tight fit between said body portion and the enclosing means; (c) a vacuum system connected to the enclosing means for generating and maintaining a predetermined negative pressure inside the enclosing means, thereby causing vasodilation in the body portion; and (d) a phase-change heat storage media for delivering thermal energy to the surface of said body portion while said vacuum system is maintaining said predetermined negative pressure, so that the local vasodilation in said body portion promotes absorption and transfer of said thermal energy from the surface of the body portion to the core body of the mammal.

Brief Description of the Drawings

Figure 1 depicts a device for treating a patient suffering from hypothermia in accordance with the present invention.

Figure 2 depicts a device for warming.

Figure 3 is a heat pipe.

Detailed Description of the Invention

Methods and devices for treating hypothermia and/or warming intravenous fluids are disclosed. The methods and devices include the use of phase-change heat transfer media.

Phase-Change Heat Storage Media

Phase-change heat storage media in accordance with the present invention include any heat storage media that will release heat slowly once heated up to its phase-change temperature. For example, phase-change media in accordance with the present invention include eutectic salts, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, and polyethylene glycol 8000. Other phase-change heat storage media include organic compounds with heats of fusion of 35 to 45 cal/g. Still other phase-change heat storage media include organic compounds with heats of fusion such that the combination of the heat of fusion with other temperature influencing parameters of the system or device are selected to achieve a suitable temperature. For example, a phase-change heat storage media could include compounds with higher heat of fusion if there are sufficient cooling influences such as conduit length between the media and the patient.

Examples of eutectic salts include sodium sulfate decahydrate (melting point 32.degree. C., heat of fusion 51 cal/g), calcium chloride hexahydrate (melting point 30.degree. C., heat of fusion 40.7 cal/g), sodium carbonate decahydrate (melting point 32.5 to 34.5.degree. C.), calcium nitrate tetrahydrate (melting point 39.7.degree. to 2.7.degree. C.) and sodium thiosulfate pentahydrate (melting point 40.degree. to 45.degree. C.). Those of ordinary skill in the art will appreciate that mixtures of eutectic salts can be made to arrive at a mixture having a desired melting point.

Other phase-change heat storage media include other salt hydrates, high density polyethylene, and CARBOWAX.™ (Union Carbide Corporation, Danbury, Conn., U.S.A.)

Other phase-change heat storage media in accordance with the present invention include those disclosed in U.S. Patent Nos. 5,424,519 and US 5,630,961 for a thermal storage mixtures that can be microwaved and maintain a constant temperature for extended periods of time.

It is also possible to use other heat storage media that do not include a phase change mechanism so long as the heat storage media is capable of maintaining an elevated temperature between 80°F and 110°F for at least 3 hours in ambient 70°F air environment.

Phase transfer heat storage media in accordance with the present invention may be stabilized in small particle sizes, e.g., 5 to 10 mm in diameter or smaller. They may also be mixed with filler materials, etc.

Microwave-Activated Intravenous Fluid Warmer

An inexpensive, easy to use, IV fluid warming system based on thermal storage technology is disclosed. The system includes a warming chamber with phase-change heat storage media and a conduit through the chamber for passing a length of intravenous tubing containing a fluid through the warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid. Since IV fluids are often run at different rates depending on the needs, size, weight and condition of the patient, several approached to maintaining an appropriate fluid temperature are contemplated. Thermal storage materials can be combined to produce the desired heat, the volume of the thermal storage material can be varied depending on the fluid flow rate, the number of packets of thermal material within the chamber can be varied, or the number of loops of IV tubing passing through the chamber can be varied. In this way, a precise temperature can be maintained at a variety of flow rates.

The fluid warming chamber includes a phase-change heat storage media or other heat storage media. The phase-change heat storage media or other heat storage media is described above and may be further insulated, encapsulated or mixed with filler. Preferably, the phase-change heat storage media is contained in a flexible bag which is microwaved and placed in the warming chamber. Standard IV tubing can then be looped in the chamber before it is closed, thus eliminating the need for a special tubing set. The number of loops contained in the chamber will be proportional to the flow rate set, to maintain a constant temperature.

The conduit is any means for passing a fluid through the warming chamber. For example, several loops of IV tubing can be passed through the warming chamber.

In use, the device could be in close proximity to the connection of the IV tubing to the IV catheter and the IV tubing would be a disposable product. The chamber could have a Velcro strap or other means to connect it to a patient's extremity, or could be worn as a glove or sleeve.

Alternatively, larger quantities of phase-change heat storage media may be used than may be comfortably worn by the patient. To accommodate the use of large amounts of phase-change heat storage media, the warming chamber may include an insulated container placed at some distance from the patient. The exact size and distance will depend on the temperature the phase-change heat storage media. For example coils of tubing in a cassette that snap into an insulated container with phase-change heat storage media inside may be used. At periodic intervals, a nurse or aide would heat several such containers in a microwave oven and then exchange the newly "charged" containers with the ones in use on patients. The cooled containers could then be re-microwaved before the next charge. This would also serve the purpose of killing all bacterial contamination, thus eliminating the need for using specific containers with specific patients.

Preferably, a thermal strip on the chamber indicates the temperature of the warming chamber. The warming chamber is also preferably designed so that the thermal storage package maintains a temperature of ~ 41C for a period of 8-12 hours and warm the fluid to ~ 37C at a fluid flow rate of 125ml/H. At the end of that time, the package would be removed and re-microwaved.

Microwaving would not only restore the thermal storage material to the desired temperature, but would also sterilize the package. Since fluids running at slower or faster rates would be warmer or cooler, respectively, the number of loops of IV tubing in the chamber could be varied, or the size of the thermal package or number of packages could be varied depending on the flow rate.

A medical port (i.e. stopcock) can also be located distal to the chamber (between it and the IV catheter) to administer medications that are heat labile.

The present invention has the advantages of low cost, simple design and operation, and easy sterilization, increased IV catheter life, reducing complications, and reducing pain.

Figure 2 depicts an intravenous fluid warmer in accordance with the present invention. Warming chamber 1 includes phase-change heat storage media 3 with an insulation coating on the outside a hinge 18, and locking mechanism 20, velcro straps 16 and conduit 4. In use, the phase-change heat storage media 3 is preheated by inserting the insulated container with inner chamber 1 into a microwave oven. Conduit 4 is placed

inside chamber 1 and closed with locking mechanism 20. Conduit 4 is then placed in-line with fusion pump 6, roller clamp 8, intravenous tubing 10, intravenous tube set 10 and intravenous bag 14.

When it is desired to place the container at some distance from the patient, thus increasing the potential for the material to cool, especially at low flow rates, various heating means may be used to provide a heated conduit between the container and the patient. For example, insulated tubing may be used. Similarly, a "heat pipe" such as that depicted in figure 3 for efficiently heating or dissipating fluid may also be used. The "heat pipe" may be connected to the insulated container and maintain the fluid in the IV tubing at a constant temperature at even a considerable distance from the patient. It may also be configured so that the conduit may be removed and the heat pipe reused.

A heat pipe, such as a copper/water type, may be used to convey heat to the conduit from the phase-change heat storage media to the i.v. fluid. The pipe may be bent to run parallel to the fluid line, and enclosed in an insulating cylinder to retain heat during transfer. This cylinder may be hinged for easy access and may also be transparent. An example is depicted in Figure 3 and includes a conduit for i.v. fluid 70, a conduit for phase-change heat storage media 72, an insulating cylinder 74 (e.g. polymethylmethacrylate) and a handle 76 for opening valves. Other heat pipes would include axially grooved heat pipes, composite heat pipes, and loop heat pipes. The use of heat pipes may require the use of a holder that anchors the heat pipe so that the additional weight of the pipe will not pull the i.v. line out of the patient.

Apparatus and Method Using a Thermal Storage Mixture for the Treatment of Hypothermia

Recently, Dennis A. Grahn of Stanford University was granted a patent, U.S. Patent No. 5,683,438 for a "Apparatus and Method for Core Body Warming of Mammals Experiencing Hypothermia", the disclosure of which is hereby incorporated by reference ("the Grahn patent"). The system described by Grahn requires a "heating means" for delivering thermal energy to a patient's extremity in an enclosed, rigid, vacuum-tight container. The heating means described both in the specification and in the claims is a circulating warm water bath, heating blanket, or heat lamp.

The enclosing means of the present invention is any means for enclosing a portion of a patients body such as an enclosing element in the form of a hollow, tubular elongated sleeve. The enclosing means is preferably particularly adapted to the shape of the body part being enclosed. The enclosing means can be formed of any material capable of sustaining the negative pressure of the vacuum, e.g. a neoprene-impregnated polyester sheath supported on a spring steel wire helix. For easier storage, an inflatable device that is rigid when inflated may be used. The enclosing means further includes means for receiving phase-change heat storage media. Such receiving means can be for example a space or void, groove, slot, etc. Any receiving means that will permit the phase-change heat storage media to come into direct or indirect contact with the patient will suffice.

Sealing means can be any means for creating an airtight seal about the enclosing means including, for example, a flexible flange. Any adhesive or "sticky" means, plus a flexible means. Shouldn't use pressure as it will reduce flow.

The vacuum system is any vacuum system capable of creating a reduced pressure within the enclosing means. Many suitable systems are known to those of ordinary skill in the art. In one embodiment, the vacuum pressure modulates to imitate circulation.

The present invention includes phase-change heat storage media for delivering thermal energy to the surface of the body. Any phase-change heat storage media as described above can be used. The use of phase-change heat storage media has several advantages over the use of a heating lamp, circulating warm water bath and warming blanket. For example, all of these other heating devices require the presence of electrical cords, tubing, or other conduits to the body surface being warmed. The present invention does not require any such conduits. The phase-change heat storage media is simply warmed at a site external from the body part being heated. The phase-change heat storage media may then be placed in direct or indirect contact (e.g. stocking as with a cast) with the body part being heated within the enclosing means. For example, the phase-change heat storage media disclosed in U.S. Patent Nos. 5,424,519 and 5,630,961 may be heated in a microwave and then inserted into the enclosing means. Phase-change heat storage materials are particularly advantageous for this application because they store large quantities of energy at a precise temperature for long periods of time. This reduces the need to change the material frequently and prevents the occurrence of skin damage.

Preferably, the phase-change heat storage media is enclosed in a thin flexible container and inserted into the enclosing means in contact with the body part being warmed. Phase-change heat transfer media are uniquely able to maintain a constant temperature over time without outside adjustment and monitoring. Once they achieve the phase transition temperature, they remain at that temperature until the phase change is complete. Therefore, there can be no overheating or under heating, which are problems with conventional electric heaters, water baths, and heating lamps.

Another benefit of the present invention over the Grahn patent is the use of a thermal storage mixture that can be microwaved. This will reduce the cost and complexity of the system by removal of the water bath components. Additionally, the thermal storage mixture is reusable and would be sterilized each time it was microwaved. Thus, a body warming system utilizing the thermal storage mixture would reduce the cost and improve the efficacy and safety of the device.

As shown in FIG. 1, a preferred embodiment of the present invention is a core body warming apparatus 10 with an enclosing element 12 in the form of a hollow, tubular, elongated sleeve. Sleeve 12 is dimensioned to fit around a body portion 62, preferably an appendage, as described below. In the embodiment illustrated in FIG. 1 appendage 62 is an arm.

Sleeve 12 can be made of virtually any non-hazardous material which retains the requisite shape while the interior of sleeve 12 is maintained at negative pressures. In particular, sleeve 12 has to support negative pressures down to at least - 85 mm Hg. In a preferred embodiment sleeve 12 is made of pliant and elastic materials which can include supporting or reinforcing members. This type of construction easily accommodates movements of arm 62 and thus provides a hypothermic patient more comfort and freedom. In the present embodiment sleeve 12 is a neoprene-impregnated polyester sheath supported on a spring steel wire helix.

Sleeve 12, as shown in FIG. 1, has a distal end or rim 14 and a proximal end or rim 16. Distal rim 14 is capped by a sealing element 60 capable of creating an airtight seal. In this embodiment element 60 is a plastic plate. However, a cap or other sealing element can be used with equal success. In fact, sleeve 12 may be closed off at distal end 14.

A flexible flange 20 is attached to proximal rim 16. Flange 20 is preferably made of a synthetic material impermeable to air. The tubular form of flange 20 ensures that it fits snugly around arm 62 and conforms to the arm's shape. In the present embodiment 20 is made of Neoprene (R).

Elongated sleeve 12 is provided with a pressure inlet 22. A pressure conduit 24, e.g., a flexible tube, is connected to inlet 22. The other end of conduit 24 is connected to a vacuum pump 26. Vacuum pump 26 is a standard pump capable of generating negative pressures down to - 85 mm Hg and beyond inside sleeve 12. The delivery of this negative pressure through conduit 24 can be regulated by any conventional mechanisms. In the embodiment shown, an adjustable valve 28 guarantees maintenance of the desired pressure inside sleeve 12. Conveniently, a readout gauge 32 is also provided for visual pressure indication.

A phase-transfer heat storage media 34 is lodged inside elongated sleeve 12. Core body warming apparatus 10 is simple to use. First, a hypothermic person's arm 62 is placed inside sleeve 12 such that the preheated phase-transfer heat storage media 34 envelops arm 62 and remains in contact with it. In this position, flange 20 wraps around the upper portion of arm 62. To ensure that flange 20 conforms closely to the contour of the upper portion of arm 62 the latter is preferably bare.

With arm 62 properly inserted into sleeve 12, pump 26 is activated to produce a negative pressure between - 20 mm Hg and - 85 mm Hg inside sleeve 12. Under the influence of negative pressure or suction, flange 20 seals tightly around the upper part of arm 62 to preserve the vacuum inside sleeve 12.

Claims

1. An intravenous fluid warming device comprising:

a) a warming chamber comprising phase-change heat storage media, and;

b) a conduit through said chamber for passing a fluid through said warming chamber with a length and diameter sufficient to provide a desired level of thermal energy to said fluid.

2. The warming device of claim 1, wherein said phase-change heat storage media comprise eutectic salt, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, or polyethylene glycol 8000 or mixtures thereof.

3. The intravenous fluid warming device of claim 1, wherein said conduit is shaped in the form of coils.

4. The intravenous fluid warming device of claim 1, wherein said chamber is an insulated chamber.

5. The intravenous fluid warming device of claim 4, wherein said insulted chamber is shaped in the form of a cassette.

6. The intravenous fluid warming device of claim 1, wherein said phase-change heat storage media is in the form of beads.

7. The intravenous fluid warming device of claim 1, further comprising a flexible bag containing said phase-change heat storage media.

8. The intravenous fluid warming device of claim 1, said conduit extending from said chamber to a patient in need of intravenous fluid administration.

9. The intravenous fluid warming device of claim 1, further comprising an intravenous port in fluid communication with said conduit.

10. The intravenous fluid warming device of claim 8, further comprising a heat pipe for warming said conduit.

11. The intravenous fluid warming device of claim 10, wherein said heat pipe is insulated.

12. The intravenous fluid warming device of claim 10, wherein said heat pipe comprises a second conduit for said phase-change heat storage media.

13. The intravenous fluid warming device of claim 1, wherein said phase-change heat storage media is microwave heatable.

14. The intravenous fluid warming device of claim 1, wherein said warming chamber is formed from said phase-change heat storage media.

15. A system for treating a mammal experiencing hypothermia, said system comprising:

a) an enclosing means for enclosing a body portion of said mammal with a means for receiving a phase-change heat storage media;

b) a sealing means mounted on said enclosing means for establishing a vacuum-tight fit between said body portion and said enclosing means;

c) a vacuum system connected to said enclosing means for generating and maintaining a predetermined negative pressure inside said enclosing means, thereby causing vasodilation in said body portion; and

d) a phase-change heat storage media for delivering thermal energy to the surface of said body portion while said vacuum system is maintaining said predetermined negative pressure, so that the local vasodilation in said body portion promotes absorption and transfer of said thermal energy from the surface of said body portion to the core body of said mammal.

16. The warming device of claim 15, wherein said phase-change heat storage media comprise eutectic salt, ethylene carbonate, glycol carbonate, 1,3-dioxolan-2-one and 1,2-ethanediol carbonate, paraffin, napthalene, crystalline polymers, or polyethylene glycol 8000 or mixtures thereof.

17. A method for core body warming of a mammal experiencing hypothermia, said method comprising the steps of:

a) enclosing a body portion of said mammal in a vacuum-tight manner, thereby defining an enclosure;

b) generating and maintaining a negative pressure within said enclosure, thereby causing a local vasodilation in said body portion; and

c) delivering a thermal energy to a surface of said body portion with a heat storage media while maintaining said negative pressure, so that said local vasodilation promotes absorption and transfer of said thermal energy from said surface to a core body of said mammal.

18. A method for intravenous administration of fluid comprising warming said fluid with a phase-change heat storage media and administering said fluid intravenously.

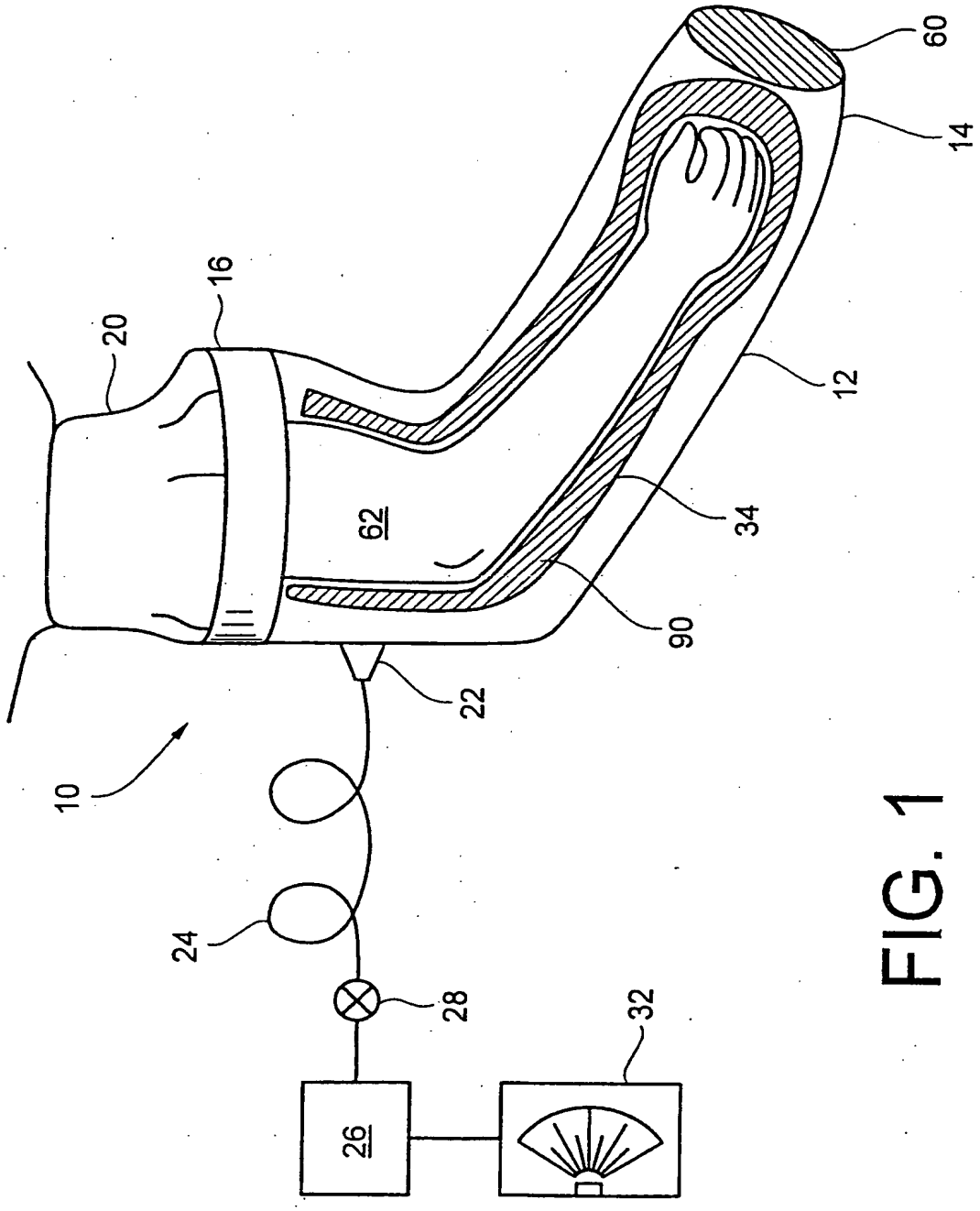


FIG. 1

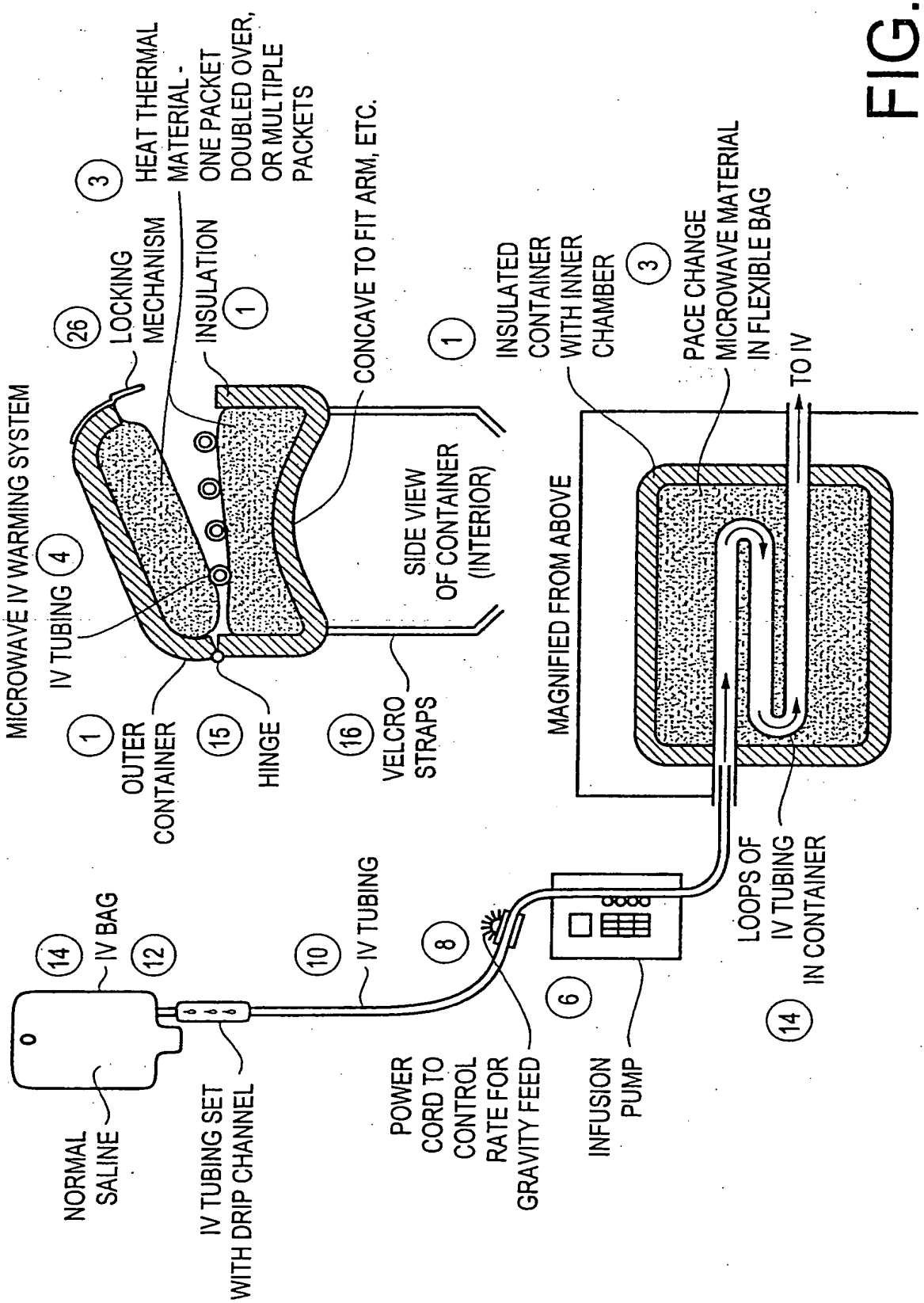
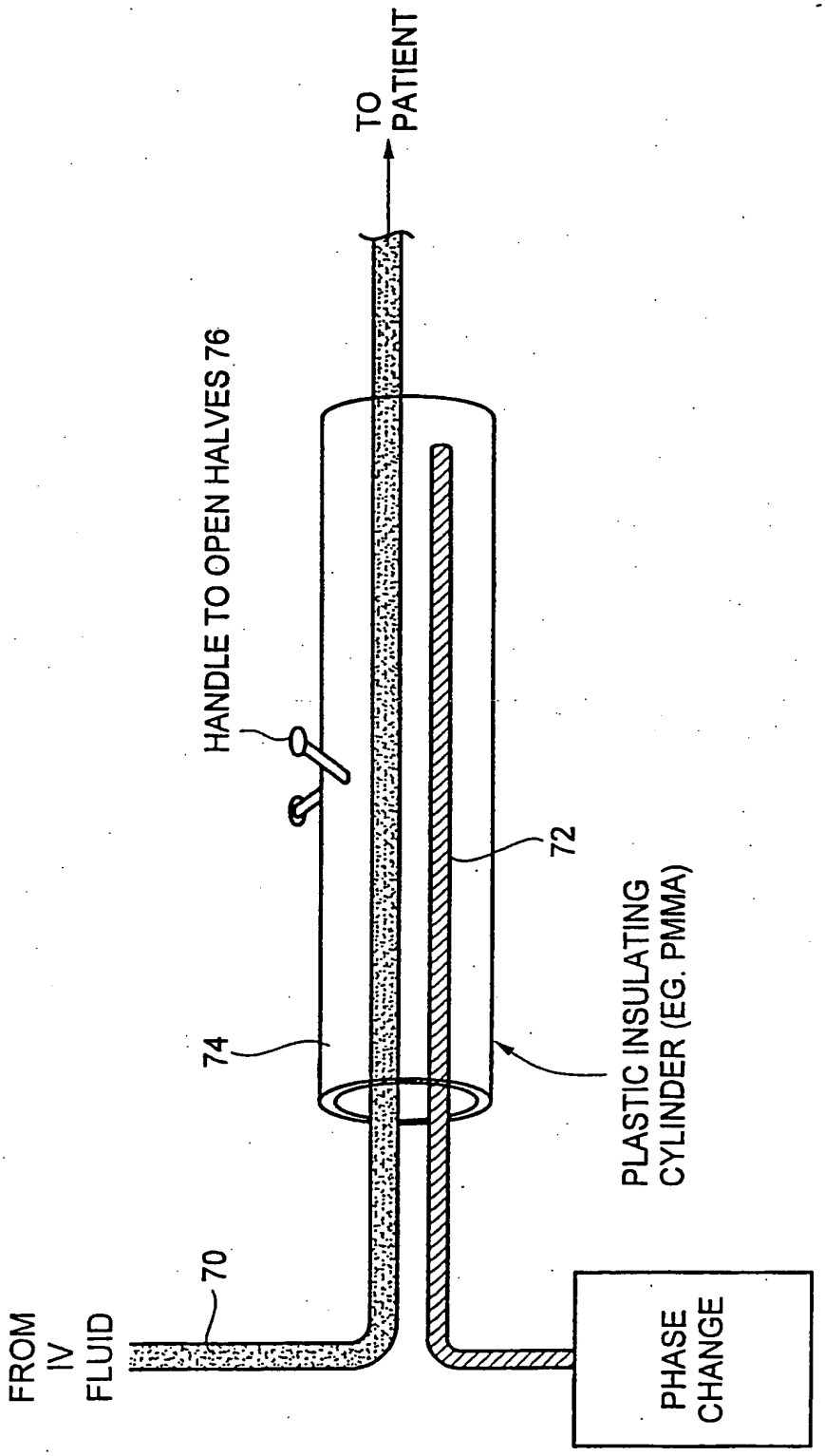


FIG. 2

FIG. 3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/03976

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 7/00
US CL :607/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/104-106, 113, 114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,370,674 A (FARRELL) 6 December 1994.	1, 3, 4, 7-14 --- 2, 5, 6, 18
X --- Y	US 5,683,438 A (GRAHN) 04 November 1997.	15 --- 16, 17
Y,P	US 5,984,953 A (SABIN et al.) 16 November 1999, col 8 lines 64-67.	2, 6, 16
Y	US 4,919,134 A (STREETER) 24 April 1990.	5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

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